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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,201	04/22/2004	Daniel J. Drucker	50821/78.4	5544

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,201	DRUCKER ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 6-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 10 June 2009 is acknowledged and entered. Following the amendment, claims 1 and 6 are amended.

Currently, claims 1 and 6-11 are pending, and claims 1 and 6 are under consideration.

Withdrawal of Objections and Rejections:

The new matter rejection of claims 1 and 6 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

The enablement rejection of claims 1 and 6 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment and argument.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the recitation "a pharmaceutical combination … comprising Gly2GLP-2 and exendin (9-39)" because it is unclear what the term encompasses. A definition for "pharmaceutical combination" is noted in the specification, which states "[T]he term "pharmaceutical combination" *embraces physical combinations* of the inhibitor and the enhancer; it is to be appreciated, however, that *other forms* of such combinations are also suitable and are embraced by the term. In one embodiment, *for instance*, the inhibitor and the enhancer are *formulated together*; in other embodiments the inhibitor and the enhancer are *formulated separately*, but associated physically for instance in kit form containing the separate formulations and instructions for their use in combination to treat a target medical condition" (page 11, [0029]). The definition uses the open language "embraces", and "for instance", which

fall within the intended definition and exemplary. Thus, such a "definition" cannot not be considered, in itself, to provide definitive scope for the "pharmaceutical combination". The metes and bounds of the claim, therefore, cannot be determined. MPEP (2171) makes it clear that the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant, which is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite, i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art. Claim 6 is similarly indefinite.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang-Christensen et al. (Nature Med., July 2000, 6(7): 802-807, provided by applicants), and in view of Drucker et al. (US5,789,379, 8/4/98).

Tang-Christensen reported a study investigating the role of GLP-2 and GLP-1 in food intake, wherein rats were centrally administered (intracerebroventricaular injection, icv) GLP-2, exendin(9-39) (a GLP-1 antagonist), or both (page 803, 2nd column, and Figure 3c, for example).

Tang-Christensen does not teach the use of Gly_2GLP-2 in combination with exendin(9-39) in the study. However, Gly_2GLP-2, like exendin(9-39), is well known in the art as a GLP-2 analog.

Drucker teaches GLP-2 analogs, which posses advantageous properties. Drucker teaches, for example, that replacing the Ala at position 2 of the GLP-2 peptide with an alternative amino acid such as Gly_2 would confer the peptide resistance to cleavage by human DPP-IV enzyme while retaining the GLP-2 activity (column 2, lines 32-33 and 56-59; claim 19, line 4; and column 15, Table 1, #4 and 6).

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a GLP-1 analog such as Gly_2GLP-2 (taught by Drucker) in combination with exendin(9-39) for studying the role of GLP-2 and GLP-1 in food intake in the experiments taught by Tang-Christensen, since Gly_2GLP-2 is a functional analog of GLP-2 (therefore, they are interchangeable). Note, the present claims do not require that the claimed pharmaceutical combination to be a mix (or a composition) of Gly_2GLP-2 and exendin(9-39). Thus, Tang-Christensen's use of the two agents together would qualify them as "a pharmaceutical combination". The person of ordinary skill in the art would have been motivated to use Gly_2GLP-2 and exendin(9-39) together for studying food intake, and potential therapeutics related to food intake, and reasonably would have expected success because Drucker has demonstrated that Gly_2GLP-2 is a GLP-2 analog possessing the functional property of GLP-2. With respect to the kit in claim 6, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said agents, because such a kit would facilitate its commercial distribution for uses such as research indicated by Tang-Christensen. Further, packing two well known agents in a kit would not be considered to constitute a novel inventive concept.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
9/30/09